Terumo Corporation
TERUMO® Hybria™ Closed System Safety I.V. Catheter
II. 510(k) Summary

APR 15 2009

Section II. 510(k) SUMMARY

A. Device Name

Proprietary Name
TERUMO® Hybria™ Closed System Safety I.V. Catheter or similar proprietary name

Classification Name
Intravascular Catheter (880.5200)
Panel & Product Code: FOZ
Classification: Class II

Common Name
Intravascular catheter with needle protection device

B. Predicate Device

The TERUMO® Hybria™ Closed System Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent with respect to intended use, design, technology/principles of operation, materials and performance to the following:

1. K991406 TERUMO® SURFLASH® I.V. Catheter
2. K923702 Becton Dickinson Saf-T-Intima Closed I.V. Catheter System
3. K032843 Becton Dickinson Nexiva Closed IV Catheter System

The differences between the devices do not raise any new issues of safety or effectiveness.

C. Intended Use

The TERUMO Hybria Closed System Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shield feature and the needleless access port aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

D. Description

The TERUMO® Hybria™ Closed System Safety I.V. Catheter is a device consisting of an over-the needle, peripheral intravascular catheter made of a slender, flexible, radio-opaque, plastic catheter, integrated extension tubing with a Y or I adaptor (needleless access port and/or filter cap available) and one touch clamp, and a passive needle-shielding mechanism.

The design of the TERUMO® Hybria™ Safety I.V. catheter can be described as a closed system since it protects clinicians and patients from blood exposure during the catheter insertion procedures. Since the needle is withdrawn through a septum that seals after the needle has been removed and ports of the Y or I adapter attached to pre-connected tubing to the IV catheter are closed, blood remains within the TERUMO® Hybria™ Safety I.V. catheter during catheter insertion.

The pressure exerted on the needle as it passes through the septum wipes blood from the needle, further reducing potential blood exposure. The one touch clamp on the integrated extension tubing is provided to minimize blood exposure when connecting with an infusion set.

E. Principle of Operation / Technology

The TERUMO® Hybria™ Closed System Safety I.V. Catheter is operated manually.

F. Design / Materials

The materials of catheter and needle on the TERUMO® Hybria™ Closed System Safety I.V. Catheter are the same materials as used in the TERUMO® SURFLASH® I.V. Catheter (K991406). The Hybria™ Closed System Safety I.V. Catheter consists of extension tubing with a Y or I adaptor (needleless access port and/or filter cap available), one touch clamp, and a passive needle-shielding mechanism. The biocompatibility of blood contacting materials were evaluated in accordance with the tests recommended in the FDA General Program Memorandum #95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".

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G. Specifications

Catheter gauge	Color code	Product code	Catheter length	Catheter O.D	Catheter I.D	Cannula gauge	Tube length
18G	Deep Green	HY*W1832SD2 HY*W1832FD2 HY*W1832CD2 HY*W1832ED2 HY*W1832GD2	1-1/4"(32mm)	1.3mm	0.95mm	20G	150mm
20G	Pink	HY*W2032SD2 HY*W2032FD2 HY*W2032CD2 HY*W2032ED2 HY*W2032GD2	1-1/4"(32mm)	1.1mm	0.80mm	22G	
22G	Deep Blue	HY*W2225SD2 HY*W2225FD2 HY*W2225CD2 HY*W2225ED2 HY*W2225GD2	1"(25mm)	0.9mm	0.60mm	24G	
24G	Yellow	HY*W2419SD2 HY*W2419FD2 HY*W2419CD2 HY*W2419ED2 HY*W2419GD2	3/4"(19mm)	0.7mm	0.47mm	27G	
18G	Deep Green	HY*S1832SD2 HY*S1832FD2 HY*S1832CD2 HY*S1832ED2 HY*S1832GD2	1-1/4"(32mm)	1.3mm	0.95mm	20G	150mm
20G	Pink	HY*S2032SD2 HY*S2032FD2 HY*S2032CD2 HY*S2032ED2 HY*S2032GD2	1-1/4"(32mm)	1.1mm	0.80mm	22G	
22G	Deep Blue	HY*S2225SD2 HY*S2225FD2 HY*S2225CD2	1"(25mm)	0.9mm	0.60mm	24G	

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Catheter gauge	Color code	Product code	Catheter length	Catheter O.D	Catheter I.D	Cannula gauge	Tube length
		HY*S2225ED2					
		HY*S2225GD2					
24G	Yellow	HY*S2419SD2	3/4"(19mm)	0.7mm	0.47mm	27G	
		HY*S2419FD2					
		HY*S2419CD2					
		HY*S2419ED2					
		HY*S2419GD2					
18G	Deep Green	HY*N1832SD2	1-1/4"(32mm)	1.3mm	0.95mm	20G	150mm
		HY*N1832FD2					
		HY*N1832CD2					
		HY*N1832ED2					
		HY*N1832GD2					
20G	Pink	HY*N2032SD2	1-1/4"(32mm)	1.1mm	0.80mm	22G	
		HY*N2032FD2					
		HY*N2032CD2					
		HY*N2032ED2					
		HY*N2032GD2					
22G	Deep Blue	HY*N2225SD2	1"(25mm)	0.9mm	0.60mm	24G	
		HY*N2225FD2					
		HY*N2225CD2					
		HY*N2225ED2					
		HY*N2225GD2					
24G	Yellow	HY*N2419SD2	3/4"(19mm)	0.7mm	0.47mm	27G	
		HY*N2419FD2					
		HY*N2419CD2					
		HY*N2419ED2					

Note: Catheter O.D. is a specification as indicated in labeling.

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Catheter gauge	Product code	Tube O.D	Tube I.D	adaptor	Connector	Wing	Flow rate	Priming volume	Lumen volume
18G	HY*W1832SD2	3.30 mm	2.10 mm	I	Needleless access port	Large Wing	58 ml/min	0.8 ml	23µl
	HY*W1832FD2				Filter cap		68 ml/min	0.9 ml	
	HY*W1832CD2				Protector cap		68 ml/min	0.8 ml	
	HY*W1832ED2			Y	Needleless access port×2		58 ml/min	1.2 ml	
	HY*W1832GD2				Needleless access port×1、Filter cap×1		58 ml/min	1.3 ml	
20G	HY*W2032SD2			I	Needleless access port		47 ml/min	0.8 ml	16µl
	HY*W2032FD2				Filter cap		50 ml/min	0.9 ml	
	HY*W2032CD2				Protector cap		50 ml/min	0.7 ml	
	HY*W2032ED2			Y	Needleless access port×2		47 ml/min	1.2 ml	
	HY*W2032GD2				Needleless access port×1、Filter cap×1		47 ml/min	1.3 ml	
22G	HY*W2225SD2			I	Needleless access port		30 ml/min	0.8 ml	7µl
	HY*W2225FD2				Filter cap		30 ml/min	0.9 ml	
	HY*W2225CD2				Protector cap		30 ml/min	0.7 ml	
	HY*W2225ED2			Y	Needleless access port×2		30 ml/min	1.2 ml	
	HY*W2225GD2				Needleless access port×1、Filter cap×1		30 ml/min	1.3 ml	
24G	HY*W2419SD2			I	Needleless access port		16 ml/min	0.8 ml	3µl
	HY*W2419FD2				Filter cap		16 ml/min	0.9 ml	
	HY*W2419CD2				Protector cap		16 ml/min	0.7 ml	
	HY*W2419ED2			Y	Needleless access port×2		16 ml/min	1.1 ml	
	HY*W2419GD2				Needleless access port×1、Filter cap×1		16 ml/min	1.3 ml	
18G	HY*S1832SD2	3.30 mm	2.10 mm	I	Needleless access port	Small Wing	58 ml/min	0.8 ml	23µl
	HY*S1832FD2				Filter cap		68 ml/min	0.9 ml	
	HY*S1832CD2				Protector cap		68 ml/min	0.8 ml	
	HY*S1832ED2			Y	Needleless access port×2		58 ml/min	1.2 ml	
	HY*S1832GD2				Needleless access port×1、Filter cap×1		58 ml/min	1.3 ml	
20G	HY*S2032SD2			I	Needleless access port		47 ml/min	0.8 ml	16µl
	HY*S2032FD2				Filter cap		50 ml/min	0.9 ml	
	HY*S2032CD2				Protector cap		50 ml/min	0.7 ml	
	HY*S2032ED2			Y	Needleless access port×2		47 ml/min	1.2 ml	
	HY*S2032GD2				Needleless access port×1、Filter cap×1		47 ml/min	1.3 ml	
22G	HY*S2225SD2			I	Needleless access port		30 ml/min	0.8 ml	7µl
	HY*S2225FD2				Filter cap		30 ml/min	0.9 ml	
	HY*S2225CD2				Protector cap		30 ml/min	0.7 ml	

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Catheter gauge	Product code	Tube O.D	Tube I.D	adaptor	Connector	Wing	Flow rate	Priming volume	Lumen volume
	HY*S2225ED2			Y	Needleless access port×2		30 ml/min	1.2 ml	
	HY*S2225GD2				Needleless access port×1、Filter cap×1		30 ml/min	1.3 ml	
24G	HY*S2419SD2			I	Needleless access port		16 ml/min	0.8ml	3μl
	HY*S2419FD2				Filter cap		16 ml/min	0.9 ml	
	HY*S2419CD2				Protector cap		16 ml/min	0.7 ml	
	HY*S2419ED2			Y	Needleless access port×2		16 ml/min	1.1 ml	
	HY*S2419GD2				Needleless access port×1、Filter cap×1		16 ml/min	1.3 ml	
18G	HY*N1832SD2	3.30 mm	2.10 mm	I	Needleless access port	Non-winged	58 ml/min	0.8 ml	23μl
	HY*N1832FD2				Filter cap		68 ml/min	0.9 ml	
	HY*N1832CD2				Protector cap		68 ml/min	0.8 ml	
	HY*N1832ED2			Y	Needleless access port×2		58 ml/min	1.2 ml	
	HY*N1832GD2				Needleless access port×1、Filter cap×1		58 ml/min	1.3 ml	
20G	HY*N2032SD2			I	Needleless access port		47 ml/min	0.8 ml	16μl
	HY*N2032FD2				Filter cap		50 ml/min	0.9 ml	
	HY*N2032CD2				Protector cap		50 ml/min	0.7 ml	
	HY*N2032ED2			Y	Needleless access port×2		47 ml/min	1.2 ml	
	HY*N2032GD2				Needleless access port×1、Filter cap×1		47 ml/min	1.3 ml	
22G	HY*N2225SD2			I	Needleless access port		30 ml/min	0.8 ml	7μl
	HY*N2225FD2				Filter cap		30 ml/min	0.9 ml	
	HY*N2225CD2				Protector cap		30 ml/min	0.7 ml	
	HY*N2225ED2			Y	Needleless access port×2		30 ml/min	1.2 ml	
	HY*N2225GD2				Needleless access port×1、Filter cap×1		30 ml/min	1.3 ml	
24G	HY*N2419SD2			I	Needleless access port		16 ml/min	0.8ml	3μl
	HY*N2419FD2				Filter cap		16 ml/min	0.9 ml	
	HY*N2419CD2				Protector cap		16 ml/min	0.7 ml	
	HY*N2419ED2			Y	Needleless access port×2		16 ml/min	1.1 ml	
	HY*N2419GD2				Needleless access port×1、Filter cap×1		16 ml/min	1.3 ml	

Note: Flow rate, priming volume, and lumen volume are specifications as indicated in labeling.

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H. Performance

The bench tests and simulated use study were performed on the TERUMO® Hybria™ Closed System Safety I.V. Catheter manufactured by Terumo Corporation to demonstrate substantial equivalence of the subject device to the predicate devices.

I. Additional Safety Information

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135-2007. The TERUMO® Hybria™ Closed System Safety I.V. Catheter is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene oxide residual levels (EtO and ECH) resulting from EtO sterilization will not exceed the maximum residue limits in accordance with ISO 10993-7: Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals and AAMI TIR19 Guidance for ANSI / AAMI / ISO 10993-7:1995, Biological Evaluation for Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (and amendment).

The addition of the safety devices requires no additional biocompatibility testing, because there is no blood/fluid contact.

J. Substantial Equivalence

The TERUMO® Hybria™ Closed System Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent to with respect to intended use, design, technology/principles of operation, materials and performance:

1. K991406 TERUMO® SURFLASH® I.V. Catheter
2. K923702 Becton Dickinson Saf-T-Intima Closed I.V. Catheter System

The differences between the devices do not raise any new issues of safety or effectiveness.

K. Submitter Information

Date Prepared: 9/30/2008

Prepared by: Eileen Dorsey
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terumo Medical Corporation
C/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

APR 15 2009

Re: **K082997**
Trade/Device Name: TERUMO® Hybria™ Closed System Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: April 1, 2009
Received: April 2, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: TERUMO® Hybria™ Closed System Safety I.V. Catheter

Indications For Use:

The TERUMO Hybria Closed System Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shield feature and the needleless access port aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Acting Branch Chief LCDR. Scott Colburn 04/15/09

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082997